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"DNA viruses"

PAT.

NO.

Title

- 1 6,369,241 T Methods for preparing antiviral calanolide compounds
- 2 6,369,195 T Prostate-specific gene for diagnosis, prognosis and management of prostate cancer
- 3 6,368,825 T Baculovirus containing minimal CMV promoter
- 4 6,368,787 **T** Methods and compositions for identifying morphogenic protein analogs using morphogenic protein responsive inhibitory elements
- 5 6,365,160 **T** Papillomavirus polyprotein constructs
- 6 H2,019 T Streptococcus pneumoniae gene sequence H11648
- 7 6,361,968 **T** Extension of a protein-protein interaction surface to inactive the function of a cellular protein
- 8 6,359,127 T MCH2, an apoptotic cysteine protease, and compositions for making and methods of using the same
- 9 6,355,781 **T** Mammalian growth factor
- 10 6,355,415 T Compositions and methods for the use of ribozymes to determine gene function
- 11 6,355,412 **T** Methods and compositions for directed cloning and subcloning using homologous recombination
- 12 6,355,252 **T** Soluble vaccinia virus protein that binds chemokines
- 13 <u>6,355,240</u> **T** Enhanced insecticidal insect virus through the expression of heterologous proteins with early promoters
- 14 6,352,856 T Chimeric poxvirus comprising sequences of a retroviral vector component
- 15 <u>6,350,866</u> **T** <u>Streptococcus pneumoniae gene sequence FtsZ</u>

- 16 6,350,575 T Helper viruses for the preparation of recombinant viral vectors
- 17 6,350,467 T Pharmaceutical preparations of glutathione and methods of administration thereof
- 18 6,348,586 T Unique associated Kaposi's sarcoma virus sequences and uses thereof
- 19 6,348,477 T Anti-herpesvirus compounds and methods for identifying, making and using same
- 20 6,348,311 T ATM kinase modulation for screening and therapies
- 21 6,344,193 T Insect control method with genetically engineered biopesticides
- 22 6,342,501 \mathbb{T} Pyrrolo[2,3-d] pyrimidines as antiviral agents
- 23 6,342,385 T Mutacin I biosynthesis genes and proteins
- 24 6,342,372 T Eukaryotic layered vector initiation systems for production of recombinant proteins
- 25 6,340,680 T Oxazinoquinolones useful for the treatment of viral infections
- 26 6,340,595 T High throughput screening of gene function using adenoviral libraries for functional genomics applications
- 27 6,339,150 T Mutant rex genes encoding transdominant repressors of HIV/HTLV replication
- 28 <u>6,339,070</u> T Gene construct encoding a heterologous prodrug-activating enzyme and a cell targeting moiety
- 29 6,339,068 T Vectors and methods for immunization or therapeutic protocols
- 30 6,339,065 T Episomal expression vector for human gene therapy
- 31 6,338,962 T Use of a non-mammalian DNA virus to express an exogenous gene in a mammalian cell
- 32 6,338,953 T Expression of an exogenous gene in a mammalian cell by use of a non-mammalian DNA virus having an altered coat protein
- 33 6,338,859 T Polymeric micelle compositions
- 34 6,337,209 T Molecular constructs containing a carcinoembryonic antigen regulatory sequence
- 35 6,337,088 T Microporous macrocapsules
- 36 <u>6,335,426</u> \mathbb{T} <u>T-cell selective interleukin-4 agonists</u>
- 37 <u>6,335,336</u> \mathbb{T} <u>3(5)-Heteroaryl substituted pyrazoles as p38 kinase inhibitors</u>
- 38 6,335,011 T Methods for delivering DNA to muscle cells using recombinant adeno-associated virus virions to treat lysosomal storage disease
- 39 6,335,010 T Gene therapy in coronary angioplasty and bypass
- 40 $\underline{6,333,194}$ T <u>Hydrogel compositions for controlled delivery of virus vectors and methods of use thereof</u>
- 41 6,331,663 T Modified full length promoters
- 42 6,329,190 T Targetting adenovirus with use of constrained peptide motifs
- 43 6,329,181 T Helper functions for recombinant vector production
- 44 6,329,173 T Method of intracellular binding target molecules
- 45 6,328,975 T Recombinant swinepox virus
- 46 6,328,958 T Deleted adenovirus vectors and methods of making and administering the same
- 47 6,328,957 \mathbb{T} Heat shock proteins and the treatment of tumors
- 48 <u>6,326,464</u> \mathbb{T} <u>P53 protein variants and the rapeutic uses thereof</u>
- 49 $\underline{6,326,354}$ T Modulation of apoptosis with bid
- 50 <u>6,326,193</u> T <u>Insect control agent</u>

United States Court of Appears for the Federal Circuit

00-1158 (Serial No. 07/631,240)

IN RE SANG SU LEE

<u>Richard H. Stern</u>, of Washington, DC, argued for Sang Su Lee. With him on the brief was <u>Robert E. Bushnell</u>.

<u>Sidney O. Johnson, Jr.</u>, Associate Solicitor, of Arlington, Virginia, argued for the Director of the U.S. Patent and Trademark Office. With him on the brief were <u>John M. Whealan</u>, Solicitor, and <u>Raymond T. Chen</u>, Associate Solicitor. Of counsel were <u>Maximilian R. Peterson</u> and <u>Mark Nagumo</u>, Associate Solicitors.

Appealed from: Patent & Trademark Office Board of Patent Appeals and Interferences

United States Court of Appeals for the Federal Circuit

00-1158 (Serial No. 07/631,240)

IN RE SANG-SU LEE

DECIDED: January 18, 2002

Before NEWMAN, CLEVENGER, and DYK, <u>Circuit Judges</u>.

NEWMAN, <u>Circuit Judge</u>.

Sang-Su Lee appeals the decision of the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office, rejecting all of the claims of Lee's patent application Serial No. 07/631,210 entitled "Self-Diagnosis and Sequential-Display Method of Every Function."[1]

We vacate the Board's decision for failure to meet the adjudicative standards for review under the Administrative Procedure Act, and remand for further proceedings. The Prosecution Record

Mr. Lee's patent application is directed to a method of automatically displaying the functions of a video display device and demonstrating how to select and adjust the functions in order to facilitate response by the user. The display and demonstration are achieved using computer-managed electronics, including pulse-width modulation and auto-fine-tuning pulses, in

accordance with procedures described in the specification. Claim 10 is representative: 10. A method for automatically displaying functions of a video display device, comprising: determining if a demonstration mode is selected;

if said demonstration mode is selected, automatically entering a picture adjustment mode having a picture menu screen displaying a list of a plurality of picture functions; and automatically demonstrating selection and adjustment of individual ones of said plurality of picture functions.

The examiner rejected the claims on the ground of obviousness, citing the combination of two references: United States Patent No. 4,626,892 to Nortrup, and the Thunderchopper Helicopter Operations Handbook for a video game. The Nortrup reference describes a television set having a menu display by which the user can adjust various picture and audio functions; however, the Nortrup display does not include a demonstration of how to adjust the functions. The Thunderchopper Handbook describes the Thunderchopper game's video display as having a "demonstration mode" showing how to play the game; however, the Thunderchopper Handbook

makes no mention of the adjustment of picture or audio functions. The examiner held that it would have been obvious to a person of ordinary skill to combine the teachings of these references to produce the Lee system.

Lee appealed to the Board, arguing that the Thunderchopper Handbook simply explained how to play the Thunderchopper game, and that the prior art provided no teaching or motivation or suggestion to combine this reference with Nortrup, or that such combination would produce the Lee invention. The Board held that it was not necessary to present a source of a teaching, suggestion, or motivation to combine these references or their teachings. The Board stated: The conclusion of obviousness may be made from common knowledge and common sense of a person of ordinary skill in the art without any specific hint or suggestion in a particular reference.

Board op. at 7. The Board did not explain the "common knowledge and common sense" on which it relied for its conclusion that "the combined teachings of Nortrup and Thunderchopper would have suggested the claimed invention to those of ordinary skill in the art." Lee filed a request for reconsideration, to which the Board responded after five years. Board reaffirmed its decision, stating that the Thunderchopper Handbook was "analogous art" because it was "from the same field of endeavor" as the Lee invention, and that the field of video games was "reasonably pertinent" to the problem of adjusting display functions because the Thunderchopper Handbook showed video demonstrations of the "features" of the game. On the matter of motivation to combine the Nortrup and Thunderchopper references, the Board stated that "we maintain the position that we stated in our prior decision" and that the Examiner's Answer provided "a well reasoned discussion of why there is sufficient motivation to combine the references." The Board did not state the examiner's reasoning, and review of the Examiner's Answer reveals that the examiner merely stated that both the Nortrup function menu and the Thunderchopper demonstration mode are program features and that the Thunderchopper mode "is user-friendly" and it functions as a tutorial, and that it would have been obvious to combine them.

Lee had pressed the examiner during prosecution for some teaching, suggestion, or motivation in the prior art to select and combine the references that were relied on to show obviousness.

The Examiner's Answer before the Board, plus a Supplemental Answer, stated that the combination of Thunderchopper with Nortrup "would have been obvious to one of ordinary skill in the art since the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software," and that "another motivation would be that the automatic demonstration mode is user friendly and it functions as a tutorial." The Board adopted the examiner's answer, stating "the examiner has provided a well reasoned discussion of these references and how the combination of these references meets the claim limitations." However, perhaps recognizing that the examiner had provided insufficient justification to support combining the Nortrup and Thunderchopper references, the Board held, as stated supra, that a "specific hint or suggestion" of motivation to combine was not required. This appeal followed.

Judicial Review

Tribunals of the PTO are governed by the Administrative Procedure Act, and their rulings receive the same judicial deference as do tribunals of other administrative agencies. <u>Dickinson V. Zurko</u>, 527 U.S. 150, 50 USPQ2d 1930 (1999). Thus on appeal we review a PTO Board's findings and conclusions in accordance with the following criteria: 5 U.S.C. §706(2) The reviewing court shall--

- (2) hold unlawful and set aside agency actions, findings, and conclusions found to be--
- (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
- (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; For judicial review to be meaningfully achieved within these strictures, the agency tribunal must present a full and reasoned explanation of its decision. The agency tribunal must set forth its findings and the grounds thereof, as supported by the agency record, and explain its application

The Administrative Procedure Act, which governs the proceedings of administrative agencies and related judicial review establishes a scheme of "reasoned decision making." Not only must

of the law to the found facts. The Court has often explained:

and related judicial review, establishes a scheme of "reasoned decisionmaking." Not only must an agency's decreed result be within the scope of its lawful authority, but the process by which it

reaches that result must be logical and rational.

Allentown Mack Sales and Service, Inc. v. National Labor Relations Bd., 522 U.S. 359, 374 (1998) (citation omitted). This standard requires that the agency not only have reached a sound decision, but have articulated the reasons for that decision. The reviewing court is thus enabled to perform meaningful review within the strictures of the APA, for the court will have a basis on which to determine "whether the decision was based on the relevant factors and whether there has been a clear error of judgment." Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 416 (1971). Judicial review of a Board decision denying an application for patent is thus founded on the obligation of the agency to make the necessary findings and to provide an administrative record showing the evidence on which the findings are based, accompanied by the agency's reasoning in reaching its conclusions. See In re Zurko, 258 F.3d 1379, 1386, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001) (review is on the administrative record); In re Gartside, 203 F.3d 1305, 1314, 53 USPQ2d 1769, 1774 (Fed. Cir. 2000) (Board decision "must be justified within the four corners of the record"). As applied to the determination of patentability vel non when the issue is obviousness. "it is

As applied to the determination of patentability <u>vel</u> <u>non</u> when the issue is obviousness, "it is fundamental that rejections under 35 U.S.C. §103 must be based on evidence comprehended by the language of that section." <u>In re Grasselli</u>, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983). The essential factual evidence on the issue of obviousness is set forth in <u>Graham v. John Deere Co.</u>, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966) and extensive ensuing precedent. The patent examination process centers on prior art and the analysis thereof. When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness. <u>See</u>, <u>e.g.</u>, <u>McGinley v. Franklin Sports, Inc.</u>, 262 F.3d 1339, 1351-52, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001) ("the central question is whether there is reason to combine [the] references," a question of fact drawing on the Graham factors).

"The factual inquiry whether to combine references must be thorough and searching." must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with. See, e.g., Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1124-25, 56 USPQ2d 1456, 1459 (Fed. Cir. 2000) ("a showing of a suggestion, teaching, or motivation to combine the prior art references is an 'essential component of an obviousness holding") (quoting C.R. Bard, Inc., v. M3 Systems, Inc., 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998)); In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."); In re Dance, 160 F.3d 1339, 1343, 48 USPQ2d 1635, 1637 (Fed. Cir. 1998) (there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant); In re Fine, 837 F.2d 1071, 1075, 5 USPQ2d 1596. 1600 (Fed. Cir. 1988) ("'teachings of references can be combined only if there is some suggestion or incentive to do so.") (emphasis in original) (quoting ACS Hosp. Sys., Inc. v. 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984)). Montefiore Hosp. The need for specificity pervades this authority. See, e.g., In re Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) ("particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed"); In re Rouffet, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("even when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination. In other words, the Board must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious."); In re Fritch, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (the examiner can satisfy the burden of showing obviousness of the combination "only by

showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references").

With respect to Lee's application, neither the examiner nor the Board adequately supported the selection and combination of the Nortrup and Thunderchopper references to render obvious that which Lee described. The examiner's conclusory statements that "the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software" and that "another motivation would be that the automatic demonstration mode is user friendly and it functions as a tutorial" do not adequately address the issue of motivation to combine. This factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority. It is improper, in determining whether a person of ordinary skill would have been led to this combination of references, simply to "[use] that which the inventor taught against its teacher."

W.L. Gore v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983). Thus the Board must not only assure that the requisite findings are made, based on evidence of record, but must also explain the reasoning by which the findings are deemed to support the agency's conclusion.

Deferential judicial review under the Administrative Procedure Act does not relieve the agency of its obligation to develop an evidentiary basis for its findings. To the contrary, the Administrative Procedure Act reinforces this obligation. See, e.g., Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Ins. Co., 463 U.S. 29, 43 (1983) ("the agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made."") (quoting Burlington Truck Lines v. United States, 371 U.S. 156, 168 (1962)); Securities & Exchange Comm'n v. Chenery Corp., 318 U.S. 80, 94 (1943) ("The orderly function of the process of review requires that the grounds upon which the administrative agency acted are clearly disclosed and adequately sustained."). In its decision on Lee's patent application, the Board rejected the need for "any specific hint or

suggestion in a particular reference" to support the combination of the Nortrup and Thunderchopper references. Omission of a relevant factor required by precedent is both legal error and arbitrary agency action. See Motor Vehicle Manufacturers, 463 U.S. at 43 ("an agency rule would be arbitrary and capricious if the agency . . . entirely failed to consider an important aspect of the problem"); Mullins v. Department of Energy, 50 F.3d 990, 992 (Fed. Cir. 1995) ("It is well established that agencies have a duty to provide reviewing courts with a sufficient explanation for their decisions so that those decisions may be judged against the relevant statutory standards, and that failure to provide such an explanation is grounds for striking down the action."). As discussed in National Labor Relations Bd. v. Ashkenazy Property Mgt. Corp., 817 F.2d 74, 75 (9th Cir. 1987), an agency is "not free to refuse to follow circuit precedent." The foundation of the principle of judicial deference to the rulings of agency tribunals is that the tribunal has specialized knowledge and expertise, such that when reasoned findings are made, a reviewing court may confidently defer to the agency's application of its knowledge in its area of Reasoned findings are critical to the performance of agency functions and judicial expertise. reliance on agency competence. See Baltimore and Ohio R. R. Co. v. Aberdeen & Rockfish R. R. Co., 393 U.S. 87, 91-92 (1968) (absent reasoned findings based on substantial evidence effective review would become lost "in the haze of so-called expertise"). knowledge and common sense" on which the Board relied in rejecting Lee's application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided do not fulfill the agency's obligation. This court explained in Zurko, 258 F.3d at 1385, 59 USPQ2d at 1697, that "deficiencies of the cited references cannot be remedied by the Board's general conclusions about what is 'basic knowledge' or 'common sense." The Board's findings must extend to all material facts and must be documented on the record, lest the "haze of so-called expertise" acquire insulation from accountability. "Common knowledge and common sense," even if assumed to derive from the agency's expertise, do not substitute for authority when the law requires authority. See

Allentown Mack, 522 U.S. at 376 ("Because reasoned decisionmaking demands it, and because the systemic consequences of any other approach are unacceptable, the Board must be required to apply in fact the clearly understood legal standards that it enunciates in principle") The case on which the Board relies for its departure from precedent, In re Bozek, 416 F.2d 1385, 163 USPQ 545 (CCPA 1969), indeed mentions "common knowledge and common sense," the CCPA stating that the phrase was used by the Solicitor to support the Board's conclusion of obviousness based on evidence in the prior art. Bozek did not hold that common knowledge and common sense are a substitute for evidence, but only that they may be applied to analysis of the evidence. Bozek did not hold that objective analysis, proper authority, and reasoned findings can be omitted from Board decisions. Nor does Bozek, after thirty-two years of isolation, outweigh the dozens of rulings of the Federal Circuit and the Court of Customs and Patent Appeals that determination of patentability must be based on evidence. This court has remarked, in Smiths Industries Medical Systems, Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1356, 51 USPQ2d 1415, 1421 (Fed. Cir. 1999), that Bozek's reference to common knowledge "does not in and of itself make it so" absent evidence of such knowledge.

The determination of patentability on the ground of unobviousness is ultimately one of judgment. In furtherance of the judgmental process, the patent examination procedure serves both to find, and to place on the official record, that which has been considered with respect to patentability. The patent examiner and the Board are deemed to have experience in the field of the invention; however, this experience, insofar as applied to the determination of patentability, must be applied from the viewpoint of "the person having ordinary skill in the art to which said subject matter pertains," the words of section 103. In finding the relevant facts, in assessing the significance of the prior art, and in making the ultimate determination of the issue of obviousness, the examiner and the Board are presumed to act from this viewpoint. Thus when they rely on what they assert to be general knowledge to negate patentability, that knowledge must be articulated and placed on the record. The failure to do so is not consistent with either effective administrative procedure

or effective judicial review. The board cannot rely on conclusory statements when dealing with particular combinations of prior art and specific claims, but must set forth the rationale on which it relies.

Alternative Grounds

At oral argument the PTO Solicitor proposed alternative grounds on which this court might affirm the Board's decision. However, as stated in Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962), "courts may not accept appellate counsel's post hoc rationalization for agency action." Consideration by the appellate tribunal of new agency justifications deprives the aggrieved party of a fair opportunity to support its position; thus review of an administrative decision must be made on the grounds relied on by the agency. "If those grounds are inadequate or improper, the court is powerless to affirm the administrative action by substituting what it considers to be a more adequate or proper basis." Securities & Exchange Comm'n v. Chenery Corp., 332 U.S. 194, 196 (1947). As reiterated in Federal Election Comm'n v. Akins, 524 U.S. 11, 25 (1998), "If a reviewing court agrees that the agency misinterpreted the law, it will set aside the agency's action and remand the case -- even though the agency (like a new jury after a mistrial) might later, in the exercise of its lawful discretion, reach the same result for a Thus we decline to consider alternative grounds that might support the different reason." Board's decision.

Further Proceedings

Sound administrative procedure requires that the agency apply the law in accordance with statute and precedent. The agency tribunal must make findings of relevant facts, and present its reasoning in sufficient detail that the court may conduct meaningful review of the agency action. In Radio-Television News Directors Ass'n v. FCC, 184 F.3d 872 (D.C. Cir. 1999) the court discussed the "fine line between agency reasoning that is 'so crippled as to be unlawful' and action that is potentially lawful but insufficiently or inappropriately explained," quoting from Checkosky v. Securities & Exch. Comm'n, 23 F.3d 452, 464 (D.C. Cir. 1994); the court explained

that "[i]n the former circumstance, the court's practice is to vacate the agency's order, while in the latter the court frequently remands for further explanation (including discussion of the relevant factors and precedents) while withholding judgment on the lawfulness of the agency's proposed action." Id. at 888. In this case the Board's analysis of the Lee invention does not comport with either the legal requirements for determination of obviousness or with the requirements of the Administrative Procedure Act that the agency tribunal set forth the findings and explanations needed for "reasoned decisionmaking." Remand for these purposes is required. See Overton Park, 401 U.S. at 420-221 (remanding for further proceedings appropriate to the administrative process).

VACATED AND REMANDED

^[1] Ex parte Lee, No. 1994-1989 (Bd. Pat. App. & Int. Aug. 30, 1994; on reconsid'n Sept. 29, 1999).